DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1219B

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50517

February 24, 1997

Joe P. Pereira
27181 East Carter Road
Escalon, California 95320-9528

WARNING LETTER

Dear Mr. Pereira:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 22 and 27, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On December 2, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 256420) for sale for slaughter as human food. This dairy cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of sulfamethazine at levels of 29.00 parts per million (ppm) in the liver and 5.00 ppm in the muscle. The analysis also revealed penicillin at 0.34 ppm in the kidney tissues. The tolerance levels have been established at 0.1 ppm for sulfamethazine and at 0.05 ppm for penicillin for the edible tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions ...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Sulfa-Max III brand of sulfamethazine that you use to treat your lactating dairy cows is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(w), and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Sulfamethazine labeling warns against using this drug in female dairy cattle twenty months of age and older. Labeling also warns against releasing dairy cattle for slaughter for food within twelve days after the last treatment. Failure to adhere to labeling directions for this drug is likely the cause of the illegal residues found in the dairy cow you sold for slaughter

The Pen-Aqueous brand of penicillin G procaine that your establishment uses on lactating dairy cows is also adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(w), and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Penicillin G procaine labeling specifies it is to be administered at a dosage of 1 milliliter (Ml) per 100 pounds of body weight and warns against using more than 10 Mls per injection site. Labeling for this drug requires a ten day withdrawal time prior to slaughter. Your practice of administering 40 Mls in an animal results in a dosage in excess of that allowed by the labeling.

Failure to adhere to labeling directions, including recommended withdrawal times, presents the possibility that illegal residues will occur makes the drugs unsafe.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports during the period of February 4, 1992, through December 3, 1996, your firm sold a dairy cow which contained violative levels of sulfamethazine and penicillin. An inspection of your dairy was conducted on April 27 and 28, 1992. During the inspection, you were warned that it is illegal to market animals containing violative levels of antibiotics in their edible tissues. A Warning Letter dated June 12, 1992, was sent to you as a result of the violations found during that inspection. Also, the U.S. Department of Agriculture (USDA) sent you a letter for each instance in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the current inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator.

Sincerely yours,

for Patricia C. Ziobro
District Director
San Francisco District

Joe Pereira Dairy
Escalon, California

cc: [redacted]